

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/534,960

03/27/00

FRIEDMAN

M

104/16

EXAMINER

HM12/0712

DR MARK FRIEDMAN LTD

C/O ANTHONY CASTORIA

2001 JEFFERSON DAVIS HIGHWAY SUITE 207

ARLINGTON VA 22202

HOWARD, S

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

07/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/534,960

Applicant(s)  
Friedman et al.

Examiner  
Sharon Howard

Art Unit  
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jun 23, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-93 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-93 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

Art Unit: 1615

## DETAILED ACTION

### *Specification*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3,12,15,18,48,56,57,60,63 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant fail to disclose in the specification, the antifungal, antibacterial, antiviral, antipsoriatic and hydrophobic water insoluble polymer derivatives.

### *Claim Rejections - 35 USC § 112*

1. Claims 1,28,47 and 93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1,47 and 93, the word "including" is indefinite because it is not established that there is a specific requirement in the claim or that it is only exemplary.

In claim 28, the phrase "selected from the group consisting of ethyl cellulose of any acceptable molecular weight" is vague and indefinite, because it is unclear as to what is meant by said phrase. Clarification is requested.

Art Unit: 1615

Applicant is requested to remove the parentheses and "w/w" and insert the words "weight by weight percent" therein in the following claims: 1(d),5,6,9,10,13,14,16,17,19,20,22-25,30,38,39,44,50,51,54,55,58,59,61,62,64,65,67-70,75,76,84,85 and 90.

It is suggested by the examiner that applicant remove the parentheses around the words "water soluble" in claims 26,27,71 and 72.

*Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6,9-17,21,26,27,29-31,33,34,36-39,41,42,46,92 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman al. (U.S. Patent No. 5,160,737) in view of Nimni (U.S. Patent No. 5,487,776).

Friedman discloses a sustained-release of pharmacological active agents, wherein the active agents are known in the art for treating fungal, bacterial or viral infections (col.7, lines 8-64). The composition comprises pharmacological agents which consists of an antifungal agent, and an antiviral agent (col.8, lines 42-56), about 1% by weight of a plasticizer (i.e. dibutyl phthalate or polyethylene glycol) (col.16, lines 18-27), water, ethyl alcohol (col.9, lines 5-13 and col.11, lines 63-65). The antifungal agent include clotrimazole, miconazole nitrate, fluconazole, ketoconazole, tolnaftate or nystatin (col.13, lines 34-47), antibacterial agents comprising

Art Unit: 1615

erythromycin, clindamycin, gentamycin, neomycin or tetracycline, and anti-viral agents which include acyclovir, amantadine or ribavirin (col.14, lines 4-7). Friedman teaches embedding the agent in a sustained release carrier comprising an acrylic polymer or a hydrophobic acrylic polymer (i.e. methacrylic acid type A copolymer), in a pharmaceutically acceptable vehicle (col.11, lines 57-61 and col.15, line 33). Friedman also discloses about 1% of humectants consisting of glycerol, sorbitol or mineral oil (col.16, lines 18-21) and that one skilled in the art would be able to produce the particular amount of each of the agents and the sustained release polymer (col.16, lines 38-40).

The method of making the sustained-release composition is an obvious and nominal step known in the pharmaceutical art.

Friedman does not teach a non-volatile solvent.

However, Nimni teaches an antifungal nail lacquer composition comprising a non-volatile solvent, benzyl alcohol (col.3, lines 64-67, col.4, lines 1-7). Nimni also teaches ethyl and isopropyl alcohol (col.3, lines 64-67, bridging col.4, line 1), copolymers of acrylic or methacrylic acid, polymethyl methacrylate (col.3, lines 58-60), a plasticizer (col.4, lines 8-12), and a film forming agent (col.3, lines 60-62).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the antifungal nail lacquer composition comprising a non-volatile solvent in the sustained release polymer composition comprising antifungal, antibacterial and antiviral agents,

Art Unit: 1615

with the expectation of achieving a sustained release composition which is known in the art for treating fungal, bacterial or viral infections.

4. Claims 1-14,16-28,30,31-45,47-91 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (U.S. Patent No. 5,023,082) in view of Hutchins et al. (U.S. Patent No. 5,863,527).

Friedman is applied as above.

Friedman does not teach a keratolytic agent.

However, Hutchins discloses skin care compositions comprising keratolytic agents which include salicylic acid, sulfur and urea (col.19, lines 25-29). Hutchins teaches that the compositions are known in the art for treating infections. Hutchins teaches from about 0.1% to about 5% of pharmaceutical active compounds. The pharmaceutical active compounds comprises antifungal agents which consist of clotrimazole, tolnaftate and nystatin, antiviral agents (col.20, lines 3-32), as well as antibacterial compounds consisting of tetracycline, clindamycin, erythromycin, metronidazole and neomycin, antipsoriatic agents comprising hydrocortisone (col.19, line 57), from about 0.1% to about 20% of a humectant comprising glycerol or sorbitol (col.22, lines 47 and 48), from about 40% to 99% of water (col.18, lines 52-58) and a volatile solvent comprising from about 5% to about 60% of ethanol, isopropanol or mixtures thereof (col.18, lines 52-54), and acetone (col.17, lines 10-12). Hutchins discloses film-forming polymers (col.26, lines 45-49).

Art Unit: 1615

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the skin care composition comprising a keratolytic agent and an antifungal agent of Hutchins in the sustained release composition comprising antifungal agents of Friedman, with the expected benefit of achieving the same beneficial results. One would expect to achieve a sustained release composition which is effective in treating fungal infections.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Howard whose telephone number is (703) 308-4359. The examiner can normally be reached on Monday-Friday from 9:00am to 5:00pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 746-3121.

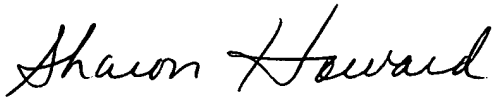
Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [[thurman.page@uspto.gov](mailto:thurman.page@uspto.gov)].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the

Art Unit: 1615


Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sharon Howard

July 9, 2001



THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600